REMARKS

In the Office Action dated March 31, 2008, the drawings and the Amendment filed December 3, 2007 were objected to because the Examiner stated the change that was made in the drawing is not supported by the specification as originally filed, and the amendment to the specification is not supported by the original disclosure. Specifically, the Examiner stated that the specification as originally filed does not support a portion of the cuff 6 being formed by a permeable membrane 6A, which was added in the previous Amendment and shown in Figure 1. The Examiner stated this constitutes new matter.

The objection to the drawings and the Amendment are respectfully traversed, for the following reasons.

Applicants respectfully submit that the specification as originally filed explicitly and unambiguously supports an embodiment wherein only a portion of the outward facing surface of the cuff 6 is formed of a permeable membrane. This is because the sentences at page 6, lines 10-13 of the original specification (which are the sentences that were amended in Applicants' previous response) originally read as follows:

> In the present embodiment the entire outward facing surface of the cuff 6 is formed of a permeable membrane 6A. In order to achieve the intended effect it is, however, sufficient for only a portion of the surface to be formed of a permeable membrane.

As also explicitly stated in Applicants' previous response, the reason why these sentences were revised, simply by reversing the content of the two sentences, was so that the permeable membrane 6A could be clearly shown in Figure 1, which the Examiner required. In Figure 1 as originally filed, the element identified by reference numeral 6A was the solid curved line, which the Examiner stated did not

clearly identify the membrane. The Examiner required that the drawings be amended to show the membrane. The specification as originally filed stated that Figure 1 shows an embodiment wherein the entirety of the outward facing surface of the cuff 6 is formed as the permeable membrane 6A. If the entirety of the solid line that was originally shown in Figure 1 were made dashed, in order to indicate the membrane 6A, then there would be nothing left in Figure 1 to indicate the cuff 6 itself.

As noted above, however, the aforementioned language in the original specification also explicitly supports an embodiment wherein only a portion of the outward facing surface of the cuff 6A is formed by the permeable membrane 6A, and this could be easily and unambiguously illustrated in the drawing, by making only a portion of the original solid line to be dashed. This is why Figure 1 was amended in that manner, and therefore it was necessary to simply reverse the sentences in the specification as originally filed, in order to state that the embodiment shown in Figure 1 is the embodiment wherein only a portion of the cuff 6 is formed by the permeable membrane 6A, and to state that in another embodiment, the entirety of the outwardly facing surface of the cuff 6 can be formed by the permeable membrane 6A.

Therefore, Applicants submit that the changes made in Applicants' previous response are unambiguously supported in the specification as originally filed, and no further changes in Figure 1 and no further changes in the specification are necessary.

Claims 1, 3-5 and 8 were rejected under 35 U.S.C. §102(b) as anticipated by or in the alternative, under 35 U.S.C. §103(a) as obvious over, Kruse et al. This rejection is respectfully traversed for the following reasons.

First, as argued in Applicants' previous response, the tube in the Kruse et al reference is for the purpose of insertion into the gastrointestinal tract of a patient, not the trachea. Consistent with that argument, claim 1 in Applicants' previous response was amended to state that the cuff is configured to be positioned in the trachea of a subject, and that the tube allows the subject to respirate.

In response, the Examiner stated that the cuff disclosed in the Kruse et al reference is "capable of being positioned" within the trachea, and the Examiner stated that the distal orifices 32 and 30 in the tube, that are shown in Figure 1 of the Kruse et al reference, would allow respiration through the tube. Applicants respectfully submit this is pure speculation on the part of the Examiner, and is actually refuted by other language in the Kruse et al reference. As stated at column 5, lines 58-60 of the Kruse et al reference, the tube or catheter 10 has a distal incorporeal end 12 which is placed within an organ or tissue of a patient's body by introduction through a body orifice, such as the nose, mouth or rectum. Despite this statement that the intracorporeal end 12 can be inserted through the mouth of a patient, in order for the alternative of insertion through the nose to be possible, this means that the extracorporeal end 12 could not have an internal channel diameter of more than a few millimeters, otherwise the tube would have an exterior diameter that would be too large for insertion through the nose. If the Examiner believes that it is possible to respirate through a tube having a diameter of a few millimeters, the Examiner is invited to locate such a tube and try to breath through it for any length of time. Applicants therefore submit that the Kruse et al disclosure supports Applicants' arguments, and does not support the Examiner's arguments.

Nevertheless, claim 1 has been amended to explicitly refer to the tube that is surrounded by the cuff as being a tracheal tube. A tracheal tube has a well known and well understood meaning to those of ordinary skill in the field of medicine, and Applicants are entitled to use that term in accordance with this well known and well understood meaning, which also implies a certain structure for such a tracheal tube. The gastoral intestinal tube disclosed in the Kruse et al reference clearly would not be considered by those of ordinary skill in the field of medicine to be the equivalent of a tracheal tube.

Also in response to Applicants' previous arguments, the Examiner referred to the statement at page 11 of Applicants' response, namely "In the subject matter of claim 1, however, it is important only that the analysis unit be able to measure a substance that has entered into the interior of the cuff from the exterior, due to the membrane." The Examiner stated this argument is not well taken because the term "only" is not supported by the claim. Applicants submit it is clear from the context of the statement made by the Applicants that Applicants were not arguing that it is necessary that the only function performed by the analysis unit is to measure a substance that has entered into the interior of the cuff from the exterior, due to the membrane. At the same page of Applicants response (page 11), preceding the sentence noted by the Examiner, the Applicants stated "The important feature of the present invention, by contrast, is to identify the content of the substance that has passed from the outside of the cuff to the interior of the cuff, so as to mix with the fluid inside of the cuff." In the sentence noted by the Examiner, therefore, Applicants were merely again pointing out that the only *necessary* feature of the analysis unit is to perform that function, namely to measure a substance that has entered into the

exterior of the cuff from the exterior, due to the membrane. Applicants were not arguing that the analysis unit does not or cannot perform any other function. Whether the analysis unit does or does not perform some other function is completely irrelevant to the patentability of claim 1.

In addition to the aforementioned editorial amendments in claim 1, claim 1 has been amended to state that the first and second tubes proceed outside of the tracheal tube and the cuff (see Fig. 1 on Replacement Sheet previously submitted). This clearly precludes continued reliance on the Kruse et al reference as either an anticipating reference or an obviating reference, since the channels in the Kruse et al catheter, that the Examiner considers to correspond to the first and second tubes in claim 1 of the present application, are internal channels (lumen) that are, and must be, in contact with the cuff disclosed in the Kruse et al reference, in order to transport fluid that is used to inflate the cuff. Such a structure is clearly unsuitable for a tracheal tube, which is why, in accordance with the present invention, the first and second tubes are located outside of the tracheal tube and the cuff.

The Kruse et al reference, therefore, does not disclose all of the elements of independent claim 1, as arranged and operating in that claim, and thus does not anticipate claim 1, nor any of claims 3-5 or 8 depending therefrom. moreover, Applicants submit that modifying the Kruse et al reference to make one or both of the internal lumens in the catheter disclosed in the Kruse et al reference proceed outside of the catheter tube would not only be a substantial redesign of the Kruse et al reference, but would most likely destroy the intended operation thereof. Therefore, modifying the Kruse et al reference in that manner, as would be necessary to conform to the language of amended independent claim 1, would not be an obvious

modification within the scope of 35 U.S.C. §103(a). Therefore, none of claims 1, 3-5 or 8 would have been obvious to a person of ordinary skill in the field of designing a tracheal insert, based on the teachings of Kruse et al, under the provisions of 35 U.S.C. §103(a).

Claim 6 was rejected under 35 U.S.C. §103(a) as being unpatentable over Kruse et al in view of Schultz, and claim 7 was rejected under 35 U.S.C. §103(a) as being unpatentable over Kruse et al in view of Hanson et al and in view of Walther et al.

The above arguments with regard to claim 1 are equally applicable to these rejections. Even if the Kruse et al device were modified in accordance with the teachings of any of these secondary references, the subject matter of claims 6 and 7, both of which embody the subject matter of claim 1 therein, still would not result.

Claims 5 and 8 were rejected under 35 U.S.C. §112, second paragraph as being indefinite for the reasons noted by the Examiner at page 3 of the Office Action. In response, claim 5 has been clarified and Applicants submit claim 5 is in full compliance with all provisions of Section 112, second paragraph.

The basis for rejecting claim 8 under Section 112, second paragraph is because the Examiner stated the limitation in lines 1-3 thereof are already present in claim 1, and that language therefore does not further limit the parent claim. Applicants submit the Examiner is mistaken in that regard. Claim 1 states that the membrane is permeable to a substance relative to the fluid and is disposed to allow transfer through the membrane of the substance from an exterior of the cuff to the interior of the cuff. Claim 8 adds the further limitation of stating that the membrane also allows transfer through the membrane of the substance from the interior of the

cuff to the exterior of the cuff. That limitation is not present in claim 1, and therefore claim 8 is in full compliance of all provisions of Section 112, second paragraph.

All claims of the application are therefore submitted to be in condition for allowance, and early reconsideration of the application is respectfully requested.

The Commissioner is hereby authorized to charge any additional fees which may be required, or to credit any overpayment to account No. 501519.

Submitted by,

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